JOHN D. CLINE (CA State Bar No. 237759)
50 California Street, Suite 1500
San Francisco, CA 94111
Telephone: (415) 662-2260 | Facsimile: (415) 662-2263
Email: cline@johndclinelaw.com

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	Case No. CR-18-00258-EJD **MS. HOLMES' NOTICE OF OBJECTION TO TX 167** Hon. Edward J. Davila

MS. HOLMES' NOTICE

On October 18, 2021, the government indicated that it will seek to introduce TX 167 into evidence through the testimony of Dr. Shane Weber. TX 167 is an internal draft Pfizer document that was never shared with Ms. Holmes or anyone else at Theranos. Ms. Holmes hereby notices her intent to object to admission of that document under Rules 401, 402, 403, 702, 802, and 805, and this Court's order requiring timely disclosure of expert witnesses. *See* Cline Decl. in Support of Ms. Holmes' Notice ("Cline Decl."), Ex. 1 (TX 167).

BACKGROUND

Dr. Weber is a former Pfizer scientist who served during the relevant time as the Director of Diagnostics in the company's Molecular Medicine Group. In December 2006, Theranos and Pfizer contracted for Pfizer to conduct "an evaluation of Theranos technology to determine its application to Pfizer's drug development efforts." TX 7753 at THER-0905833 (in evidence). The nearly two-year project entailed assay development and validation by Theranos, Theranos' participation in a Pfizer-sponsored clinical trial, and Theranos' compilation of a final report. *See id.* at THER-0905834, THER-0905842-44. Theranos' participation in the study concluded in early October 2008, and Theranos submitted the final report and associated assay data on October 11, 2008. Cline Decl., Ex. 2 (TX 143).

Dr. Weber was not involved in any of that work. As TX 167 notes, Theranos had multiple Pfizer contacts since 2005—none of whom were Dr. Weber. Cline Decl., Ex. 1 at 3. Rather, Dr. Weber was introduced to Theranos only in November 2008, after the work was completed. Over the subsequent six weeks, he conducted a review comprised of what he described as "a one[-]hour teleconference" with Theranos; review of the Theranos study report, publicly available patents, and Theranos' answers to 25 related follow-up questions; and conversations with unnamed Pfizer colleagues who, unlike Dr. Weber, purported to have previously interacted with Theranos. *See generally id.* Following that review, Dr. Weber drafted TX 167, a seven-page internal document dated December 31, 2008.

Dr. Weber's document states that its "purpose . . . was to close the loop on all previous efforts for Theranos to look for business opportunities with Pfizer, and to make final recommendations regarding potential future attempts for Theranos to engage different parts of Pfizer in their platforms."

Cline Decl. Ex. 1 at 1. The document reflects Dr. Weber's view that no such business opportunities existed, but that his group intended to "monitor[]" the Theranos-Pfizer relationship "[g]oing forward." *Id.* The document does not purport to evaluate Theranos' technology or the data generated in the Theranos-Pfizer clinical study. It does contain, however, inflammatory hearsay statements from Dr. Weber and others concerning their view of "Theranos'" business marketing and the quality of its written deliverables. *See id.* at 1-2. Dr. Weber is likely to testify that he conveyed to Ms. Holmes by telephone that no immediate business opportunities existed at Pfizer for Theranos, but that he did not convey the internal document to anyone at Theranos.

MS. HOLMES' OBJECTIONS

Rules 401-402: There is no evidence that Ms. Holmes was shown TX 167, or that it was transmitted to Theranos. As a result, this document is not probative of the allegation that Ms. Holmes "knew that these pharmaceutical companies and research institutions had not examined, used, or validated Theranos technology." *See* Dkt. 469, ¶ 12(H). The Court has held that other evidence that is unconnected to Ms. Holmes is inadmissible, and should do the same here. *See, e.g.,* Dkt. 798 at 66-67 (trade secrets); *id*. at 63-64 (alleged "bad acts" of certain Theranos employees).

Rule 403: Even if TX 167 has some minimal probative value, that value is far outweighed by the unfair prejudice associated with its admission. Again, Ms. Holmes did not receive, review, or endorse Dr. Weber's document, and the document does not establish that Pfizer ultimately did not validate Theranos technology. Dkt. 469, ¶ 12(H).

On the other side of the ledger, TX 167 threatens to mislead the jury and inflict substantial unfair prejudice on Ms. Holmes. First, TX 167 is replete with language that—although bearing no relevance to the ultimate issues in the case—will have the effect of inflaming the jury and suggesting bad conduct on the part of unidentified individuals at "Theranos." *See, e.g*., Cline Decl. Ex. 1 at 1 (describing "Theranos" as "excessively pushy"); *id.* at 2 (characterizing the company's "conclusions in their summary document" as "not believable"); *id*. (accusing "Theranos" of furnishing "non-informative, tangential, deflective or evasive answers to a written set of technical due diligence questions").

Second, TX 167 makes sweeping statements about "Pfizer's" course of dealing with Theranos—

despite the fact that, by Dr. Weber's own admission, TX 167 reflects his personal recommendations based on his personal review and conversations with colleagues, not a memorialization of the reasons for any final decision by Pfizer decisionmakers concerning the company's relationship with Theranos. *See* Ex. 3 at 2-3 (8/24/2021 MOI) ("[Dr. Weber] recognized the document as a summary of his position for [three Pfizer executives]. . . . This was his final report and his conclusions never changed. . . . Weber said the . . . 'Recommendations' were clear recommendations for review by directors and other company vice presidents. . . . He did not know if anyone within Pfizer had overruled his recommendations . . . ."). These sweeping statements may mislead the jury to conclude that the document is a final formulation of Pfizer's position, when, in reality, it is nothing more than a summary of Dr. Weber's personal conclusions subject to revisiting.

Last, because the government has argued that Pfizer was "saying no" directly to Ms. Holmes, 9/8/2021 Gov't Opening Statement Tr. 534:17-20, the jurors may wrongly assume that Ms. Holmes received the document. Jurors may also wrongly interpret the document as bearing on the indictment allegation—*i.e.*, as reflecting "Pfizer's" view of Theranos' technology performance (which it does not do)—as opposed to reflecting the more limited (and less relevant) conclusion that, in Dr. Weber's opinion and in the opinion of the "two oncology Therapeutic Area Molecular Medicine Leads" to whom he spoke, there were no apparent business opportunities for Theranos at Pfizer in December 2008. Cline Decl. Ex. 1 at 1. These inferences would be contrary to the evidence.

Rule 702, Dkt. 171: TX 167 contains statements based on specialized knowledge that will require explanation to lay jurors. *See, e.g.*, Ex. 1 at 2 (referencing "Sutent and other anti-EGFR receptor or anti-angiogenesis therapies"); *id*. (discussing "working nucleic in vitro diagnostic assay platforms" and "molecular test needs of the Pan Her and CDX-110 studies" and "Maraviroc tropism tests"). The government has not disclosed Dr. Weber as an expert, contrary to the Court's order requiring timely disclosure of experts, Dkt. 171, and has given no indication of how it would satisfy the requirements of Rule 702.[1]

[1] Rule 702 applies even if the Court concludes that the document is a business record. *See Clark v. City of Los Angeles*, 650 F.2d 1033, 1037 (9th Cir. 1981) ("Expressions of opinion or conclusions in a business record are admissible only if the subject matter calls for an expert or professional opinion and

Rules 802, 805: Because there is no evidence that Ms. Holmes was shown TX 167, Ms. Holmes presumes that the government seeks to introduce the document for the truth of the matter asserted. For the reasons set forth below, the document is inadmissible as a business record. And even if the document were a business record, it contains double hearsay from other Pfizer employees, and it is unclear how the government could overcome the hearsay bar for those statements.

Numerous facts indicate that this document is not a "record[] of a regularly conducted activity." Fed. R. Evid. 803(6). First, Dr. Weber drafted TX 167 well after the events that the document purports to assess—not "at or near the time" of those activities. Fed. R. Evid. 803(6)(A); *see Willco Kuwait (Trading) S.A.K. v. deSavary*, 843 F.2d 618, 628 (1st Cir. 1988) (district court did not abuse discretion in concluding that a telex was not a business record because, *inter alia*, the telex referred to an "investigation and report which occurred more than three months before"); *United States v. Lemire*, 720 F.2d 1327, 1350 (D.C. Cir. 1983) (document summarizing background of dealings between two counterparties, and explaining reasons for the award of a contract, was inadmissible as a business record, because it recounted events that had occurred as long as one year and ten months before drafting).

Second, TX 167 bears the hallmarks of an ad-hoc document, not one "made pursuant to established company procedures for the systematic or routine and timely making and preserving of company records." *Clark v. City of Los Angeles*, 650 F.2d 1033, 1037 (9th Cir. 1981). Dr. Weber's document is the product of a standalone, onetime review, rather than a routine, standardized, company process. Documents created under such circumstances are not business records. *See* Fed. R. Evid. 803 Advisory Committee's Note ("Absence of routineness raises lack of motivation to be accurate.").

Third, the document is, on its face, a preliminary document. Although Dr. Weber's prior statement describes TX 167 as "his final report," the document has all the indicia of a draft, not subject to Fed. R. Evid. 803(6). Cline Decl. Ex. 3 at 2. The document contains typographical errors, bears a stamp "Subject to Ongoing Management Review," and, according to that prior statement, reflects only Dr. Weber's recommendation to his superiors at Pfizer. *Id*. at 2. For these reasons, TX 167 lacks the reliability expected of documents subject to Fed. R. Evid. 803(6).

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is given by one with the required competence.").

/s/ John D. Cline
JOHN D. CLINE
Attorney for Elizabeth Holmes

CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2021 a copy of this filing was delivered via ECF on all counsel of record.

/s/ John D. Cline
JOHN D. CLINE
Attorney for Elizabeth Holmes